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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,956	12/23/2003	Yin Chen	CRYA,025/CIP	9376

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CYTOGENIX, INC.
3100 WILCREST DRIVE
SUITE 140
HOUSTON, TX 77042

EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,956	CHEN ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-3,12-15,18,19,25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-11,16,17 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/21/2006; 4/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 8/7/2006; 1/24/2007; 5/7/2007. Claims 1-26 are pending. Claims 1-3, 12-15, 18-19, 25-26 are withdrawn. Claims 4-11,16-17,20-24 are examined herein.

Election/Restrictions

Applicant's election with traverse of invention III (claims 4-11), drawn to vectors and expression hosts in the reply filed on 8/7/2006 is acknowledged. The traversal is on the ground(s) that a prior art search for the discrete single stranded DNA-zyme SEQ ID 7, such as set forth in claim 13 of invention IV would be coextensive with a search for the double stranded vectors of invention III. This is not found persuasive because the DNA-zyme(s) of unelected claim 12 of invention IV is broadly drawn to 15 nucleotide catalytic domains, requiring an extensive search not required for a thorough consideration the double stranded vectors and expression hosts of invention III.

In the amendment entered 8/7/2006, applicant introduced claims 18-19 drawn to the single stranded DNA reverse transcribed (expressed) by the bacterial ssDNA expression vector of invention III.

Said single stranded DNA versus the bacterial ssDNA expression vector of invention III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, said product may be made by methods such as chemical synthesis.

In the amendment entered 8/7/2006, applicant introduced claims 25-26 drawn to a method for treating a bacterial infection using a composition comprising the bacterial ssDNA expression vector of invention III.

Said method of treating a bacterial infection and the bacterial ssDNA expression vector of invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case a treatment of bacterial infection may be performed using antibiotics.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper and is therefore mailed FINAL.

During a telephone conversation with Cyndee Ewell on 8/16/2007 it was decided claims 18-19 and 25-26 will withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Specification

The amendment filed 8/7/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment

shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: on p 8 and 9 applicant has added a reference to US Patent Application serial no. 10/136,218 in regard to plasmid pssXE.

Applicant has inserted a new flowchart on p 7 of the specification, which the Examiner agrees serves to clarify aspects of the claimed invention, however applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure in accordance with MPEP 714.02, paragraph 5, last sentence and MPEP 2163.06 I.

In the reply to this Office Action, Applicant is required to cancel the new matter and/or point out support therefor, specified as to page and line in the disclosure as originally filed.

Claim Rejection(s) – 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-11,16-17,20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The plasmid pssXGb of claim 16 is essential to the claimed invention and must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the plasmid is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials. The specification does not disclose a repeatable process to obtain the plasmid and it is not apparent if the plasmid is readily available to the public. Further, the plasmid deposit must be made under the Budapest Treaty, and an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

Claims 4-11,16-17,20-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 35 USC 132 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claim 4 has been amended on 8/7/2006 to be drawn to a bacterial single-stranded DNA expression vectors.

While the disclosure as filed discusses double stranded vectors, such as pssXGb, it is noted however the specification as originally filed provided no implicit or explicit support for single stranded DNA vectors, such as set forth in the preamble to claim 4.

Claims 20-23 each comprise a carrier, whereas the specification as originally filed provided no implicit or explicit support for pharmaceutically acceptable excipients (i.e. carriers)

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

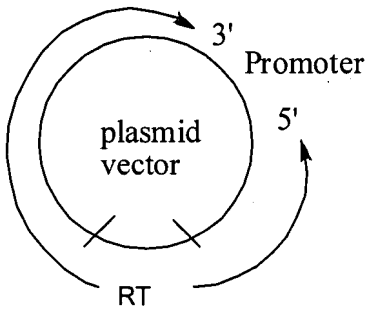
MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection

based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-11,16-17,20-24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships concern plasmids, such as pSSXGb of the present disclosure which are inherently circular thus 5' and 3' positional limitations, such as set forth in claim 4(b-c) are ambiguous, and thus indefinite: the circular topology makes all loci simultaneously 5' and 3' to one another. See figure below. (RT is reverse transcriptase)



Due to the indefiniteness detailed above, claim 4 and all dependent claims are rejected under 35 USC 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6, 7, 10, 11, 16, 17, 20-21, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Conrad (WO 00/22114 – IDS entry 2/21/2006).

The claimed subject matter per claim 4 is drawn to bacterial single-stranded DNA (ssDNA) expression vector comprising:

(a) an inducible bacterial promoter;

(b) a genetic sequence encoding a fully active reverse transcriptase (RT), located 3' of the inducible bacterial promoter; and

(c) a ssDNA expression cassette for producing a ssDNA inside a cell, located 3' to the RT sequence and comprising in 5' to 3' order:

(i) a set of inverted tandem (IT) repeats for formation of a stem-loop structure,

(ii) a cloning site for cloning a sequence of interest (SOI), and

(iii) a primer binding site (PBS) sequence sufficient for initiation of reverse transcription inside a bacterial cell..

Claims 6, 7, 10, 11, 16, 17, 20-21, 23-24 represent variations thereof.

Conrad teaches, throughout the document and especially p 1, a method of producing single-stranded DNA in yeast, prokaryotes (bacteria) and eukaryotic cells using plasmids, such shown in figure 4.

Conrad teaches in claim 5, inducible promoters which are taken as the inducible bacterial promoter set forth in claim 4 (a). Conrad teaches in figure 1, a genetic construct including in 5' to 3' order: reverse transcriptase, such as set forth in claim 4(b); a single-stranded expression element comprising inverted repeats, a sequence of interest and primer binding sites, such as set forth in claim 4 (c).

Conrad teaches in figure 3, a DNA enzyme which targets RNA, comprising SEQ ID 7 flanked by 13 nucleotides, which is taken as meeting the limitations set forth in claims 7 and 10.

Conrad teaches cells transformed with said genetic construct in claims 59-61, reading on claims 6 and 11.

The genetic composition of pssXGb, shown in figure 2 of the present application includes a gene for chloamphenicol resistance, in addition to the stem-loop forming inverted repeats and reverse transcriptase mentioned above. Conrad teaches chloamphenicol resistance genes on p 26, line 23, therein reading on claim 16.

It is noted that claim 17 is drawn to SEQ ID 13 or "a fragment thereof." Even one nucleotide is considered a fragment thereof, thus absent evidence to the contrary, plasmids such as pssDNA-Express-A, shown in figure 4 of Conrad would include the fragment 5'-C-3', of SEQ ID 13.

Conrad teaches carriers in claim 79, reading on claim 20-21 and 23-24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 6, 7, 10, 11, 16, 17, 20-21, 23-24 and 8,22 rejected under 35 U.S.C. 103(a) as being unpatentable over **Conrad** (WO 00/22114 –IDS entry 2/21/2006) in view of **RayChaudhuri et al** (US Patent Application 2006/0252114).

Conrad is relied on as above.

Conrad teaches carriers in claim 79, such as set forth in claim 22.

Conrad does not teach targeting bacterial FtsZ genes (claim 8), however.

RayChaudhuri et al teach, throughout the document and especially paragraph 0018, compounds for inhibiting FtsZ in bacteria.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use the method of producing single-stranded DNA in bacteria cells per Conrad to discover single-stranded DNAs which inhibit FtsZ in bacteria per RayChaudhuri et al.

One of ordinary skill in the art would have been motivated to use the method of producing single-stranded DNA in bacteria cells per Conrad to discover single-stranded DNAs which inhibit FtsZ in bacteria per RayChaudhuri et al because there is an urgent need for the identification of compounds having anti-microbial activity, as noted by RayChaudhuri et al in paragraph 0009.

One of ordinary skill in the art would have had a reasonable expectation of success in combining the method of producing single-stranded DNA in bacteria cells per Conrad to discover single-stranded DNAs which inhibit FtsZ in bacteria per RayChaudhuri et al because the inhibitors elucidated by RayChaudhuri et al are effective against *E. coli* which is the same organism favored by Conrad.

Claims 4, 6, 7, 10, 11, 16, 17, 20-21, 23-24 and 5 rejected under 35 U.S.C. 103(a) as being unpatentable over **Conrad** (WO 00/22114 –IDS entry 2/21/2006) in view of **Nakagawa et al** (European Patent Application EP 1 108 790 A2).

Conrad is relied on as above.

Conrad does not teach a vector comprising SEQ ID 3 as a primer binding site as set forth in claim 5, however.

Nakagawa et al teach, throughout the document and especially the abstract, shotgun sequencing of the *Corynebacterium glutamicum* genome, which comprises SEQ ID 3 of the present application, indicated in as SEQ ID 3471 according to Nakagawa et al (see also CAS Registry print-out)

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to incorporate SEQ ID 3 as a PCR priming site for shotgun sequencing of *Corynebacterium glutamicum* per Nakagawa et al using the plasmids according to Conrad.

One of ordinary skill in the art would have been motivated to incorporate SEQ ID 3 as a PCR priming site for shotgun sequencing of *Corynebacterium glutamicum* per Nakagawa et al using the plasmids according to Conrad because *Corynebacterium glutamicum* are useful in preparing various valuable compounds, such as glutamic acid, a delicious seasoning, according to Nakagawa in paragraph 0003.

One of ordinary skill in the art would have had a reasonable expectation of success in incorporating SEQ ID 3 as a PCR priming site for shotgun sequencing of *Corynebacterium glutamicum* per Nakagawa et al using the plasmids according to Conrad because it is noted that both Nakagawa et al (i.e. see p 10-11) and Conrad utilize *E. coli* for genetic manipulations.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-6,16-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 66-67,71-75, 79 of copending Application No. 10/574,254 (referred to as '254) .

Although the conflicting claims are not identical, they are not patently distinct from each other because, for example, claims 4-6,16-17 represent structural variants of all that is recited in claims 66-67,71-75, 79 of '254 or, alternatively overlap in scope to a large extent and, as a result, the overlapping claims would be rendered obvious.

For **claim 4**, the '254 application claims a vector comprising a bacterial promoter, reverse transcriptase, inverted repeats, a cloning site and a primer binding site (e.g. see claims 66,67,71-72).

For **claim 5**, the '254 application claims SEQ ID 3 (e.g. see claim 71).

For **claim 6**, the '254 application claims a cell having said vector (e.g. see claim 79).

For **claims 16-17**, the '254 application claims the vector pssXG (e.g. see claim 75). It is noted that claim 17 is drawn to SEQ ID 13 or "a fragment thereof." Even one nucleotide is considered a fragment thereof, thus absent evidence to the contrary, plasmids such as pssXG of the '254 application would include the fragment 5'-C-3', of SEQ ID 13, for instance.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify embodiments of '254 that fall outside the scope of the present application to select a specifically disclosed embodiment that falls within the scope of the present application because these embodiments describe vectors with similar biological activity (i.e. production of single-stranded DNA). Furthermore, one of ordinary skill in the art would have been motivated to make such a modification because such modifications are disclosed as "preferred" since the dependent claims of the '254 application "teach toward" Applicant's claimed vectors (e.g. see claim 73-74 drawn to tetracycline inducible promoters).

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg
/Jon D. Epperson/
Primary Examiner, AU 1639